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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/890,088	07/26/2001	Alessandro Lambiase	026073.00020	6075

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ARENT FOX LLP
1050 CONNECTICUT AVENUE, N.W.
SUITE 400
WASHINGTON, DC 20036

EXAMINER
WOODWARD, CHERIE MICHELLE

ART UNIT	PAPER NUMBER
1647	

NOTIFICATION DATE	DELIVERY MODE
04/29/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DCIPDocket@arentfox.com
IPMatters@arentfox.com
Patent_Mail@arentfox.com

Office Action Summary	Application No.	Applicant(s)	
	09/890,088	LAMBIASE, ALESSANDRO	
	Examiner	Art Unit	
	CHERIE M. WOODWARD	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 August 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13-15,18-21,24-27 and 30-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13-15,18-21,24-27 and 30-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Please note that the examiner of this Application has changed. Please direct all correspondence to CHERIE M. WOODWARD, Art Unit 1647. Additional contact information is provided below.

Continued Examination Under 37 CFR 1.114

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/22/2008 has been entered.

Formal Matters

3. Claims 1-12, 16, 17, 22, 23, 28, and 29 have been cancelled. Claims 13-15, 18-21, 24-27, and 30-36 are pending and under examination.

Advisory Notice

4. No translation has been provided for the Foreign Priority Document – Italy RM99A00069 (1/29/1999). See, 35 USC 119(b)(3).

Response to Arguments

Rejections/Objections Withdrawn

5. Rejections drawn to cancelled claims 17, 23, 28, and 29 are moot in light of Applicant's cancellation of these claims.

Rejections/Objections Maintained

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 13-15, 18-21, 24-27 and 30-36 remain rejected under 35 U.S.C. 102(b) as being anticipated by Lambiase (WO 98/48002), as evidenced by Steadman's Medical Dictionary (Lippincott

Williams & Wilkins, 2000) and *The World's Best Anatomical Charts* (Anatomical Chart Company, Skokie, IL, 2000) (Sagittal View of the Eye), for the reasons of record and the reasons set forth herein.

Applicant argues that the claim amendments directed to specifically recited pathologies are sufficient to overcome the rejection (Remarks, pp 6-7). Applicant argues that the '022 publication only discloses treatment of corneal and conjunctival tissues (Remarks, p. 7). Applicant argues *Perricone v. Medicis Pharmaceutical Corp* (Fed. Cir. 2005) for the proposition that treatment of corneal tissue is not inherent treatment of internal tissues of the eye (Remarks, p. 8).

Applicant's arguments have been fully considered, but they are not persuasive. Regarding Applicant's argument that the '002 publication is drawn to treatment of corneal and conjunctival tissues, which Applicant states are not "internal tissues" of an eye. Applicant's arguments are contradictory to the claims, as written. Applicant has amended the claims to recite specific pathologies. These pathologies include perforating trauma of the sclera. The sclera has also been previously recited in the claims as an "internal tissue". To elucidate this contradiction, Applicant's attention is drawn to p. 2 of the '002 publication, lines 12-14, which recites a broader definition of "cornea" than the limited one argued by Applicant. The '002 publication teaches that the cornea encompasses not only epithelium and stroma/keratocytes, but also endothelium, which is clearly an "internal tissue". See, for evidentiary purposes only, Steadman's Medical Dictionary, 2000, definitions of cornea and endothelium. See also, (for visual reference) the Sagittal View of the Eye on page 17 of *The World's Best Anatomical Charts* (Anatomical Chart Company, Skokie, IL, 2000) (cited for evidentiary purposes only). According to the anatomical definitions provided by Steadman's Medical Dictionary and the visual anatomical representation of the Sagittal View of the Eye, the cornea is anatomically continuous with the sclera. Moreover, given that the broad definition of the cornea in the '002 publication encompasses the corneal endothelium, it is unclear how Applicant can argue that the sclera is an "internal" issue, but not the cornea or at the very least, the corneal endothelium is not an "internal" tissue. Accordingly, the '002 publication teaches treatment of "internal" tissues of the eye, which include tissues that are continuous anatomically with the sclera. The teachings of the '002 publication showing that treatment of NGF treats corneal tissues, including corneal endothelium, is a sufficient basis for the examiner to assert and maintain an anticipatory inherency argument.

The evidentiary references cited herein are provided to establish inherency of the claimed method (see *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed Cir 1999)). The examiner also notes that there is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of invention, but only that the subject matter is in fact inherent in the prior

art reference. See also, *Schering Corp. v. Geneva Pharm. Inc.*, 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003) (rejecting the contention that inherent anticipation requires recognition by a person of ordinary skill in the art before the critical date and allowing expert testimony with respect to post-critical date clinical trials to show inherency).

Given the teachings of the evidentiary references set forth above, along with the teachings of the '002 publication itself, Applicant's citation of *Perricone v. Medicis Pharmaceutical Corp* (Fed. Cir. 2005) is not on point with the facts in the instant case and is therefore not applicable.

Regarding Applicant's arguments that the claim amendments directed to specifically recited pathologies are sufficient to overcome the rejection, the '002 publication teaches pathologies that include situations that may interfere with normal eye integrity including trauma, surgery, or laser treatment. In light of the '002 publication's broad definition of "cornea" as including the endothelial stratum, which is an internal structure of the eye, and the evidentiary references, which show that the cornea is continuous with the sclera, the '002 publication inherently anticipates treatment of pathologies of the sclera, including perforating trauma of the sclera. Further, the '002 publication provides additional evidence that treatment of "internal tissues" were contemplated by the '002 publication because administration of NGF by induction to the anterior chamber of the eye is taught at page 12, lines 17-20.

8. Claims 13-15, 18-19, 21, 24-27, and 30-36 remain rejected under 35 U.S.C. 102(b) as being anticipated by Finkenaur et al. (EP 0312208 A1), as evidenced by *The World's Best Anatomical Charts* (Anatomical Chart Company, Skokie, IL, 2000) (Sagittal View of the Eye), for the reasons of record and the reasons set forth herein.

Applicant argues that the '208 publication teaches the use of gels for topical or incisional wound healing at sites that are in the anterior chamber of the eye and that these tissues are not tissues that are internal tissues of the eye (Remarks, p. 10). Applicant argues that the '208 publication does not inherently anticipate the instantly claimed invention (Remarks, p. 10). Applicant argues *Perricone v. Medicis Pharmaceutical Corp* (Fed. Cir. 2005) for the proposition that treatment of tissues taught by the '208 publication is not inherent treatment of internal tissues of the eye (Remarks, p. 8). Applicant argues that the claim amendments directed to specifically recited pathologies are sufficient to overcome the rejection (Remarks, p. 11).

Applicant's arguments have been fully considered, but they are not persuasive. Regarding Applicant's argument that the '208 publication is drawn to treatment of the anterior chamber of an eye and that the anterior chamber is not an "internal tissue," Applicant's arguments are contradictory to the

claims, as written. Applicant has amended the claims to recite specific pathologies. These pathologies include perforating trauma of the sclera. The sclera has also been previously recited in the claims as an "internal tissue". To elucidate this contradiction, Applicant's attention is drawn to the Sagittal View of the Eye on page 17 of *The World's Best Anatomical Charts* (Anatomical Chart Company, Skokie, IL, 2000) (cited for evidentiary purposes only). The visual anatomical chart shows that the anterior chamber of the eye is behind (posterior to) the cornea and portions of the anterior chamber actually lie behind (posterior to) the sclera. The sclera is encompassed in the instant claims as an "internal tissue" of an eye. Additionally, Applicant's list of specifically recited pathologies includes wounds to the sclera, "perforating trauma of the sclera." Accordingly, the '208 publication teaches treatment of "internal" tissues of the eye, which includes tissues that are continuous to or anatomically lie even with or behind the sclera. The '208 publication clearly teaches administration of a gel or eye drop formulations including solutions comprising NGF, to treats "other surgically induced wounds in the eye" (p. 6, line 7), internal incisions and internal wounds (p. 6, lines 10-11) which would inherently encompass the claimed recited pathology of "perforating trauma of the sclera." Perforating trauma of the sclera is inherently encompasses within the teachings of wound healing in the anterior chamber of the eye (abstract) as well as internal incisions and wounds (page 6, lines 9-11), in view of the anatomical structure of the eye, as evidenced by the Sagittal View of the Eye.

The evidentiary reference cited herein is provided to establish inherency of the claimed method (see *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed Cir 1999)). The examiner also notes that there is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of invention, but only that the subject matter is in fact inherent in the prior art reference. See also, *Schering Corp. v. Geneva Pharm. Inc.*, 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003) (rejecting the contention that inherent anticipation requires recognition by a person of ordinary skill in the art before the critical date and allowing expert testimony with respect to post-critical date clinical trials to show inherency).

Given the teachings of the evidentiary reference set forth above, along with the teachings of the '208 publication itself, Applicant's citation of *Perricone v. Medicis Pharmaceutical Corp* (Fed. Cir. 2005) is not on point with the facts in the instant case and is therefore not applicable.

New Objections/Rejections

Specification

9. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The word "use" in the title is not appropriate for US practice, as a "use" is non-statutory under 35 USC 101.

The following title is suggested: Method of Treating Intraoccular Tissue Pathologies with Nerve Growth Factor.

Claim Rejections - 35 USC § 112, First Paragraph

Written Description - New Matter

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 13, 21, and 25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The claims have been amended to include the recitation of retinitis pigmentosa. However, there is no disclosure of retinitis pigmentosa in the specification. Accordingly, the recitation of retinitis pigmentosa represents new matter.

Obviousness-Type Double Patenting Rejection

12. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In*

re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

13. Claims 13, 15, 18 19, 20, 21, 24-27, 30, 31, 33, 35, and 36 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 8-11, and 13 of copending Application No. 12/064,172. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are drawn to a method of treating optic neuritis, which is a condition of the CNS (i.e. treatment of the optic nerve). Instant claims 13, 21, 25, and 33 correspond to claim 1 of the '172 application. Instant claims 15 and 27 correspond to claim 8 of the '172 application. Instant claims 18, 19, 24-26, 30, 31, 35, and 36 correspond to claims 9-11 of the '172 application. Instant claims 20 and 32 correspond to claim 13 of the '172 application. It is also noted that the claims of the '172 application are non-statutory "use" claims (see 35 USC 101). However, for the purposes of the instant rejection, the examiner reads the "use: claims of the '172 application as method claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

NO CLAIM IS ALLOWED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHERIE M. WOODWARD whose telephone number is (571)272-3329. The examiner can normally be reached on Monday - Friday 9:30am-6:00pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on (571) 272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Cherie M. Woodward/
Primary Examiner, Art Unit 1647